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| 09/864,680 | 05/24/2001 | Brian J. Staskawicz | 42250/234021 (5830-4A) | 2026 |

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,680

Applicant(s)

STASKAWICZ ET AL.

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☒ Claim(s) 1 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-3 are pending in this application and are under examination.

Sequence Listing

Applicant's CRF and paper sequence listing have been entered. However, the disclosure, for example, page 29, lines 9, 12, and 20-21 recites sequences without sequence identifier or SEQ ID NO:. Applicants must submit a new CRF and paper copy of the Sequence Listing, including said sequence. Applicants must also amend the specification to include the SEQ ID NO for these sequences.

Objections

The disclosure is objected to because it contains an embedded hyperlink. For example, page 10, lines 1 and 15, cites hyperlink directed to an Internet address. The use of hyperlinks and/or other forms of browser-executable code are not permitted under USPTO current policy. Therefore, Applicant is required to delete the embedded hyperlink. See MPEP § 608.01.

Claims 1-3 are objected to because the claims recite more than one period. It is suggested that "Seq.ID No." be changed to ---SEQ ID NO:---.

Information Disclosure Statement

Initialed and dated copy of Applicant's IDS form 1449, Paper No.3 is attached to the instant Office action.

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Drawings

1. The drawings filed with this application have been approved.

Claim Rejections - 35 USC § 112

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated protein comprising the amino acid sequence set forth of SEQ ID NO:3, does not reasonably provide enablement for an isolated protein comprising an amino acid sequence having at least 85% sequence identity to the amino acid sequence of SEQ ID NO:3 and having Bs2 biological activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed isolated protein comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:3 and still retaining Bs2 biological activity is not supported by an enabling disclosure taking into account the *In re Wands* factors (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or

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unpredictability of the art, and the breadth of the claims. In the specification, Applicant provided guidance for the isolated protein encoded by the nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1, 2 or 4 having Bs2 biological activity. Applicant has not provided guidance for any modifications to SEQ ID NO:3 that resulted a protein having 85% sequence identity to SEQ ID NO:3 and still retaining Bs2 biological activity. An isolated protein having 85% sequence identity to SEQ ID NO:3 include those obtainable by modifications including additions, deletions, and substitution of several amino acids in SEQ ID NO:3. The working example disclosed in the instant specification is limited to unmodified SEQ ID NO:3. Therefore, it is unpredictable as to whether any amino acid substitutions, additions, or deletions in a protein will retain the protein activity. The state of the art as exemplified by Lazar et al. (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U)) and Broun et al. (Science, 13 November 1998, Vol. 282, pp. 131-133 (W)), teach unpredictability inherent in protein function when one or more amino acids in that protein is modified. Lazar et al teach a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al teach as few as four amino acid substitutions can change an oleate 12-desaturase activity (Abstract). Therefore, absent any specific guidance as to which region in SEQ ID NO:3 can be modified so as Bs2 biological activity is retained, one skilled in the art would not be able how to make the claimed product, without undue experimentations.

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Therefore, given the breadth of the claims; the lack of guidance; the unpredictability; the state of the art as discussed above; and the limited working examples, undue trial and error experimentations would have been required by one skilled in the art to obtain a protein having 85% sequence identity with SEQ ID NO:3 and still having Bs2 biological activity.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to any isolated protein comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:3 and still retaining Bs2 biological activity. The specification only described the protein having the amino acid sequence of SEQ ID NO:3 encoded by a nucleotide sequence from *Capiscum annuum*. The specification does not disclose any specific structural, physical and/or chemical

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properties for the claimed sequence, other than that it has 85% sequence identity to the disclosed sequence. While the claim recites functional language, it is unclear if all proteins having at least 85% sequence identity to SEQ ID NO:3 will exhibit the recited functional activity. Therefore, the written description requirement is not satisfied. Therefore, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention.

See Written Description Requirement published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111). See, also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Remarks

Claims 1-3 are free of the prior art of record.

Claims 1 and 3 would be allowable if the objection is obviated.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00AM to 4:00PM and Wednesday-Thursday from 9:00AM to 3:00 PM .

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

September 18, 2002
mai


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800